

*A2
CONT.*

7. (Amended) A flavor enhancer obtainable by allowing a culture product of the isolated koji mold according to any one of claims 1 to 4 to act on a protein.

REMARKS

Claims 1-2 and 4-5 have been amended to replace the term "gene" with "nucleic acid sequences." Support can be found for the term "nucleic acid sequences" on page 6, first full paragraph of the specification.

Claims 2-7 have also been amended to provide the term "isolated koji mold" to provide proper antecedent basis when referring to the transformed koji mold having increased protease activity and peptidase activity as recited in claim 1. Thus, the amendments do not introduce new matter.

Claims 2 and 4 have been amended to clarify that the protease and peptidase nucleic acid sequences are "of koji mold origin." Support can be found in the sentence bridging pages page 6 and 7.

Applicants hereby address each point raised in the Office Action of March 28, 2002.

On page 2 of the Office Action, the abstract was objected to because it contains more than one paragraph. Correction has been made and the abstract contains less than one hundred fifty words.

Claims 5-7 are rejected under 35 U.S.C. § 112, first paragraph, because the claims allegedly embrace "any and all peptidase fragments, variants or derivatives of proteases and peptidases from any source whatsoever." The Office contends that the specification does not teach a representative number of nucleic acids encoding peptidases or proteases that would encompass the wide array of molecules claimed and therefore, the written description requirement has not been satisfied.

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The Office seems to require that the specification describe "the complete structure of a representative number of species" to satisfy the written description requirement. However, the written description requirement looks to the invention that is claimed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), and *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997). See also MPEP § 2163. As recognized by the Office on page 2, Applicants claim a method of breeding a Koji mold (claim 5), a method of manufacturing a flavor enhancer (claim 6), and a flavor enhancer (claim 7). Applicants are not claiming *per se* the protease and peptidase nucleic acids. Indeed, they do not because the instantly claimed method works with any protease or peptidase nucleic acid, as long as they express in and are secreted from a koji mold (see paragraph bridging pages 6 and 7). The identity of the protease or peptidase nucleic acid is not part of the invention and the issue is not whether Applicants have identified those protease and peptidase nucleic acids. Thus, the instant situation is fundamentally unlike *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993), and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200 (Fed. Cir. 1991), where claims were directed to nucleic acid or protein sequences and therefore were required to provide adequate written description of those molecules themselves. Claims 5-7 recite methods and a flavor enhancer. The specification provides sufficient description of the instantly claimed methods and flavor enhancer.

Withdrawal of the rejection is respectfully requested.

Claims 1-7 are rejected under 35 U.S.C. § 112, first paragraph, for recitation of the term "gene." The Office contends that "gene" refers to not only a coding sequence but also to an entire genomic structure. The Office kindly suggested that Applicants replace the term "gene" with "nucleic acid sequence." Applicants have amended the claims accordingly and the rejection is now rendered moot. Withdrawal of the rejection is respectfully requested.

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Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for use of the terms "peptidase" and "protease." The Office contends that the terms are redundant. Applicants respectfully disagree. On page 2, first full paragraph of the specification, the terms "protease" and "peptidase" are clearly defined: a "protease" "acts to roughly cleave and dissolve proteins" whereas a "peptidase" "further breaks down amino acids from the termini of peptides." In other words, a peptidase acts after the protease has broken down a protein into peptides and cleaves amino acids from the ends of the peptides. Thus, the terms are not redundant and describe different enzymatic activities. Withdrawal of the rejection is kindly requested.

Claims 2 and 4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the recitation of "derived from a koji mold." The Office contends that the lack of the nature and number of derivations make the metes and bounds of the claims indefinite. Applicants wish to provide clarification that the term "derived" in these claims is used to mean "obtained from koji mold" or "originating from koji mold", rather than suggesting derivations of protease and peptidase genes. Thus, claims 2 and 4 have been amended to recite "wherein the protease nucleic acid and the peptidase nucleic acid are of koji mold origin." Support can be found in the sentence bridging pages 6 and 7 ("it is preferable that the gene be of koji mold origin"). Thus, withdrawal of the rejection is respectfully requested.

Claim 4 is rejected because it is unclear as to whether the protease and peptidase nucleic acid sequences are from the same species of koji mold as recited in claim 3. Applicants wish to clarify that the protease and peptidase nucleic acid sequences recited in claim 4 may be from any koji mold and not limited only to those recited in claim 3. In order to make this point clear, Applicants have amended claims 2-7 to recite "isolated koji mold" when referring to the isolated koji mold having increased protease activity and peptidase activity of claim 1. By contrast, the

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protease and peptidase nucleic acid sequences are of "koji mold origin" and not limited to the "isolated koji mold." Applicants kindly request withdrawal of the rejection.

Claims 1-4, 6 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by JP 53124693 (the '693 patent). The Office contends that the '693 patent anticipates the instant claims because the '693 patent discloses a koji mold having increased peptidase and protease activity.

A finding of anticipation under 35 U.S.C. § 102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987). This standard precludes any finding of anticipation of the instant claims by the '693 patent. The instant claims require "transformation with a protease nucleic acid sequence and a peptidase nucleic acid sequence." The '693 patent fails to satisfy this element. The '693 patent utilizes bean curd waste or its decomposition product in order to increase protease and peptidase activity. The '693 patent does not use nucleic acid sequences of any kind. The '693 does not teach transforming koji mold with a protease and peptidase nucleic acid sequence to increase protease and peptidase activity. It merely teaches mixing bean curd waste with soy beans (see abstract). Thus, the '693 patent does not anticipate the instant claims. Withdrawal of the rejection is kindly requested.

Claims 1-7 are rejected under 35 U.S.C. § 102(e) as being anticipated by Van Den Broek et al. (U.S. Patent No. 6,090,607). The Office contends that Van Den Broek discloses a koji mold that exhibits increased exopeptidase and endopeptidase activity after transforming the koji mold with single or multiple areA genes. Applicants respectfully traverse.

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As discussed above, the instant claims require "transformation with a protease nucleic acid sequence and a peptidase nucleic acid sequence." By contrast, Van Den Broek transforms koji mold with the *areA* gene, which encodes a DNA-binding protein belonging to the GATA family of transcription factors (column 2, lines 24-26). Thus, the *areA* gene is not a protease nucleic acid sequence or a peptidase nucleic acid sequence. Van Den Broek teaches increasing exopeptidase and endopeptidase activity by modulating *areA* expression because *areA* regulates expression of proteolytic enzymes (see, for example, Example 1). But nowhere does Van Den Broek transform or suggest to transform koji mold with protease or peptidase nucleic acid sequences. Van Den Broek therefore does not anticipate the instant claims. Withdrawal of the rejection is kindly requested.

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

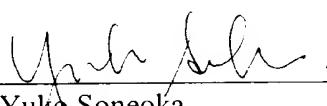
The undersigned has been given limited recognition under 37 C.F.R. § 10.9(b) to prosecute this patent application. That document granting limited recognition is enclosed herewith.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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By:


Yuko Soneoka
Limited Recognition under
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Dated: June 25, 2002

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APPENDIX TO AMENDMENT OF JUNE 25, 2002

Version with Markings to Show Changes Made

Amendments to the Claims

1. (Amended) An isolated koji mold having increased protease activity and peptidase activity in relation to a parent strain resulting from transformation with a protease [gene] nucleic acid sequence and a peptidase [gene] nucleic acid sequence.
2. (Amended) The isolated koji mold according to claim 1, wherein the protease [gene] nucleic acid sequence and the peptidase [gene] nucleic acid sequence are [derived from a] of koji mold origin.
3. (Amended) The isolated koji mold according to claim 1, wherein said isolated koji mold is a member of *Aspergillus sojae*, *Aspergillus oryzae*, or *Aspergillus tamarii*.
4. (Amended) The isolated koji mold according to claim 3, wherein the protease [gene] nucleic acid sequence and the peptidase [gene] nucleic acid sequence are [derived from a] of koji mold origin.
5. (Amended) A method of breeding the isolated koji mold according to any one of claims 1 to 4 comprising the steps of:
 - (a) transforming a parent strain of koji mold with a protease [gene] nucleic acid sequence and a peptidase [gene] nucleic acid sequence; and,

(b) selecting a transformant having increased protease activity and peptidase activity relative to said parent strain.

6. (Amended) A method of manufacturing a flavor enhancer which comprises allowing a culture product of the isolated koji mold according to any one of claims 1 to 4 to act on a protein.

7. (Amended) A flavor enhancer obtainable by allowing a culture product of the isolated koji mold according to any one of claims 1 to 4[,] to act on a protein.

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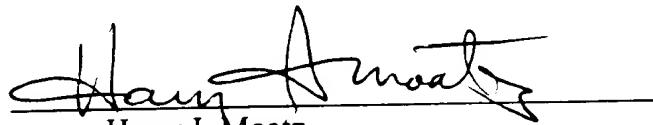
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LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)

Yuko Soneoka is hereby given limited recognition under 37 CFR § 10.9(b) as an employee of Finnegan, Henderson, Farabow, Garrett & Dunner LLP to prepare and prosecute patent applications wherein the patent applicant is the client of Finnegan, Henderson, Farabow, Garrett & Dunner LLP, and the attorney or agent of record in the applications is a registered practitioner who is a member of Finnegan, Henderson, Farabow, Garrett & Dunner LLP. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Yuko Soneoka ceases to lawfully reside in the United States, (ii) Yuko Soneoka's employment with Finnegan, Henderson, Farabow, Garrett & Dunner LLP ceases or is terminated, or (iii) Yuko Soneoka ceases to remain or reside in the United States on an H-1 visa.

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Expires: August 27, 2002


Harry I. Moatz
Director of Enrollment and Discipline